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**From:** Schaeffer, Dennis CIV [Dennis.Schaeffer@dtra.mil]  
**Sent:** Friday, August 23, 2002 2:37 PM  
**To:** 'NIOCINDOCKET@CDC.GOV'  
**Subject:** Comments on 42 CFR Part 83



42 CFR 83  
comments.DOC

**Defense Threat Reduction Agency provides the attached comments on proposed rules for 42 CFR Part 83.**

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comments.DOC>>**

NIOSH has made significant suggestions toward the development of regulations implementing the provisions of the EEOICPA that address additions to the Special Exposure Cohort – in its proposed rule 42 CFR Part 83, presentations to the Advisory Board for Radiation and Worker Health, and in public meetings. However, a major difficulty has emerged in coordinating the interpretation of requirements for SEC additions listed in EEOICPA Section 3626: “(1) it is not feasible to estimate with sufficient accuracy the radiation dose that the class received; and (2) there is a reasonable likelihood that such radiation dose may have endangered the health of members of the class.” The obvious question is how endangerment is established without accurate doses.

NIOSH proposes a scheme on 42 CFR 83 “to establish an objective measure of health with minimal use of subjective expert judgment...fairly, transparently, and consistently as possible.” However, because this scheme relies on a specific determination of dose, it meets these criteria less well than does the following approach, which is based on the principle, *any dose that can be upper-bounded is sufficiently accurate*, and its corollary, *any dose that cannot be upper-bounded is perforce a reasonably likely endangerment to health*. As applied to a worker’s eligible cancer(s) under the EEOICPA, these mean that (1) if all dose(s) to the pertinent body organ(s) can be upper-bounded, then the provisions of 42 CFR 81&82 are sufficient for processing the claim; and (2) any contribution to dose that cannot be upper-bounded to a pertinent organ provides a technical basis for initiating a class eligible for addition to the SEC. It is evident that ascertaining whether an upper-bound dose does exist more straightforwardly and better meets NIOSH’s criteria than does calculating a specific dose and the consequent risk.

The following are noted in conjunction with this approach:

- (1) NIOSH has indicated its intent to proactively identify the membership of a class (here the set of workers sharing an exposure with an unbounded contribution to dose to the pertinent organ[s]), based on its commonality with a worker for whom a dose reconstruction cannot be completed.
- (2) The determination of an upper-bound dose, if feasible, and its application to a specific claim in the absence of information for more accurately estimating the dose are consistent with the provisions of 42 CFR 82, specifically parts 82.10, 82.12, 82.14, and 82.16.
- (3) The retrospective endangerment of health (e.g., for a specific cancer already incurred) logically applies to a compensation program, whereas the prospective endangerment of health (e.g., the incremental risk of incurring any cancer from future exposures) applies to a worker safety program.

In most instances, including all that involve penetrating gamma radiation, an unbounded dose to one organ will imply unbounded dose to all organs, thereby providing a clear and simple application of the above principles. If, however, the unbounded component of dose is solely due to radionuclides deposited in certain organs only, then only for these organs are 42 CFR 81&82 not sufficient for processing a claim. In this situation, the cancers associated with these organs only are logically relevant to a potential SEC class. Such a differentiation based on cancer type is technically sound, unambiguous in its application, fair to workers and the Government, *and nowhere contraindicated by the provisions of the EEOICPA*. Note that the Health Physics Society provided NIOSH

suggestions in 2001 (published on the NIOSH/OCAS website) for implementation of the EEOICPA, including Section 3626, that differentiated by cancer classes for potential inclusion in the SEC. The approach proposed herein is in accordance with NIOSH's 42 CFR 83 criteria and limits the situations in which this cancer dependence is germane.

On the basis of the above, three simple modifications to the proposed rule 42 CFR 83 are recommended:

- (1) include in part 83.5 a definition of "sufficiently accurate dose" and an expanded definition of "endangered the health" in accord with the stated principles; and
- (2) eliminate 83.12(b)(1), which through these principles is supplanted by (b)(2), in which "estimated" becomes "estimated or upper-bounded."
- (3) add a brief description of the criteria that will be applied to decide whether or not an upper-bounded dose can be estimated.